IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CARDIONET, INC., et al. CIVIL ACTION

No. 12-2517 v.

MEDNET HEALTHCARE

TECHNOLOGIES, INC., et al.

MEMORANDUM

Juan R. Sánchez, J. November 15, 2013

In this patent infringement action, Plaintiffs CardioNet, Inc., and Braemar Manufacturing, LLC, sue Mednet Healthcare Technologies, Inc., MedTel 24, Inc., RhythmWatch LLC, Heartcare Corporation of America, Universal Medical Inc., Universal Medical Laboratory, Inc., and AMI Cardiac Monitoring, Inc., for infringing five patents originally owned by CardioNet, which CardioNet assigned to Braemar during the pendency of this action.1 The patents-in-suit—U.S. Patent Nos. 7,212,850 (the '850 patent), 7,907,996 (the '996 patent), 6,569,095 (the '095 patent), 7,587,237 (the '237 patent), and 7,941,207 (the '207 patent)—relate to different aspects of remote patient cardiac monitoring. Plaintiffs allege Defendants have infringed and are continuing to infringe each of these patents by making, using, selling, and/or offering for sale the Heartrak External Cardiac Ambulatory Telemetry (Heartrak ECAT) System, which consists of a device that records and processes a patient's electrocardiographic (ECG) signal and monitoring service for assessing the cardiac data transmitted by the device.

¹ On December 31, 2012, CardioNet assigned all right, title, and interest in the five patents-insuit to Braemar, and Braemar granted CardioNet an exclusive license to make, use, offer to sell, sell, import, license, and exploit the patents-in-suit.

The parties have submitted a total of eleven claim terms for construction by this Court, though they do not agree all of the submitted terms require construction.² The parties have also agreed to constructions for three additional claim terms. Following a claim construction hearing on February 20, 2013, and for the reasons set forth below, the Court will construe the disputed claim terms as set forth herein.

CLAIM CONSTRUCTION PRINCIPLES

"[C]onstruction of a patent, including terms of art within its claim[s], is exclusively within the province of the court." Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996). In construing a patent claim, "the words of [the] claim 'are generally given their ordinary and customary meaning," which is the meaning they would have "to a person of ordinary skill in the art in question at the time of the invention." Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Where claim language has an ordinary meaning that is "readily apparent even to lay judges," claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." Id. at 1314. A claim term that has a readily apparent plan meaning may not require construction. ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc., 694 F.3d 1312, 1325-26 (Fed. Cir. 2012) (holding a district court did not err in declining to construe claim terms upon concluding the terms had plain meanings that did not require additional construction). Where the meaning of a claim term as understood by a person of skill in the art is not immediately apparent, however, the court must "look[] to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean," including intrinsic evidence such

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² Plaintiffs contend six of the submitted terms need not be construed. Defendants assert one of the terms does not require construction.

as "the words of the claims themselves, the remainder of the specification, [and] the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips*, 415 F.3d at 1314 (citations and internal quotation marks omitted).

The Federal Circuit has emphasized the importance of intrinsic evidence in claim construction, noting such evidence "usually provides the technological and temporal context to enable the court to ascertain the meaning of the claim to one of ordinary skill in the art at the time of the invention." *See id.* at 1313-17 (quoting *V-Formation, Inc. v. Benetton Grp. SpA*, 401 F.3d 1307, 1310 (Fed. Cir. 2005)).

The claims themselves provide substantial guidance as to the meaning of particular claim terms by defining the context in which the terms (which are typically used consistently throughout the patent) are used. *Id.* at 1314. Differences among claims can also shed light on the meaning of particular claim terms, such as when a dependent claim adds a particular limitation, "rais[ing] a presumption that the limitation in question is not found in the independent claim." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004); *see also Phillips*, 415 F.3d at 1314-15.

The claims must also "be read in view of the specification, of which they are a part." *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 979). Not only is the specification "always highly relevant to the claim construction analysis," but "[u]sually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* (quoting *Vitronics*, 90 F.3d at 1582). When, for example, the specification "reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess, . . . the patentee's lexicography governs." *Id.* at 1316. Similarly, where the specification reveals "an intentional

disclaimer, or disavowal, of claim scope by the inventor, ... the inventor's intention, as expressed in the specification, is regarded as dispositive." *Id.* While a court must read a patent's claims in light of its specification, the court must also take care not to import limitations from the specification into the claims, such as by confining claims to preferred embodiments disclosed in the specification where the claim language has broader effect. *Id.* at 1323; *see also Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004) (holding "particular embodiments appearing in [a patent's] written description will not be used to limit claim language that has broader effect," even where the patent describes only a single embodiment, "unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction" (internal citations and quotation marks omitted)). At the same time, the claims cannot "enlarge what is patented beyond what the inventor has described as the invention." *Impro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350, 1355 (Fed. Cir. 2006) (internal citation and quotation marks omitted).

The intrinsic evidence relevant to claim construction also includes the patent's prosecution history, which "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

In addition to considering intrinsic evidence, a court may also rely on extrinsic evidence in construing patent claims, including dictionaries, learned treatises, and expert testimony. *Id.* at 1317-18. Expert testimony, for example, may be useful "to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to

establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field"; however, "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful." *Id.* at 1318. Because such evidence is generally less reliable than the intrinsic evidence, the Federal Circuit has cautioned "it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1319.³

DISPUTED CLAIM TERMS

A. The '850 and '996 Patents

The '850 and '996 patents, which share a common title⁴ and specification, describe "systems and techniques relating to processing and presenting arrhythmia event information from physiological data." '850 Patent col.1 ll.18-20.⁵ The asserted claims of the patents are directed to methods, articles, and systems for processing and pictographically presenting information regarding arrhythmia events, including atrial fibrillation events, to assist medical practitioners in treating such events. The patents disclose ways of presenting information regarding heart rate data and duration of atrial fibrillation events together with a common time scale "to pictographically represent heart rate trend with atrial fibrillation burden during a

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³ Here, both parties have submitted expert declarations in support of their proposed claim constructions. The Court has considered the declarations, in which the experts offer their competing opinions as to how a person of ordinary skill in the art would understand the disputed claim terms in the context of the patents. Because the experts' use of the intrinsic record to support their opinions is also reflected in the briefing, the declarations are cited only sparingly herein.

⁴ Both patents are titled, "System and Method for Processing and Presenting Arrhythmia Information to Facilitate Heart Arrhythmia Identification and Treatment." The '996 patent issued from a continuation of the application that led to the '850 patent.

⁵ Because the '850 and '996 patents share a common specification, for ease of reference, citations to the common specification are to the '850 patent.

defined time period." *Id.* col.1 ll.45-49. Many of the asserted claims of the '850 patent call for the information to be selectively presented based on a "measure of correlation" between machine-identified arrhythmia events and human-assessments of at least a portion of such events. *See*, *e.g.*, *id.* col.6 ll.15-19. The asserted claims of the '996 patent call for the information to be presented based on a human assessment of a subset of identified atrial fibrillation events. *See*, *e.g.*, '996 Patent col.6 ll.7-8.

1. "Measure of Correlation"

The term "measure of correlation" appears in asserted claims 1 and 20 of the '850 patent and is used in the same manner in both. Claim 1 recites:

1. A machine-implemented method comprising:

identifying atrial fibrillation events in physiological data obtained for a living being;

obtaining heart rate data for the living being; and

pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of atrial fibrillation activity, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden;

wherein presenting information comprises selectively presenting the information based on a *measure of correlation* between the identified atrial fibrillation events and human-assessments of at least a portion of the identified atrial fibrillation events.

'850 Patent col.6 ll.5-20 (emphasis added).

The term "measure of correlation" is not expressly defined in the '850 patent. Defendants argue the claims and specification nevertheless reveal that the patentee used the term to mean a "calculated value representing how closely two data sets match." Defs.' Opening Claim Construction Br. 8. Defendants argue the claims themselves demonstrate that a measure of correlation must be a "value" because a majority of the independent claims of the '850 patent

⁶ The parties agree the prosecution history of the '850 patent does not illuminate the meaning of this term.

include a step requiring a comparison of the measure of correlation to a "predetermined value," thereby suggesting the "measure of correlation" must also be a value. See, e.g., '850 Patent col.6 II.58-61 (calling for information to be selectively presented based on a measure of correlation "if the measure of correlation matches or exceeds at least one predetermined value"). Defendants contend the specification reinforces this interpretation and, in addition, confirms the measure of correlation must be a calculated value because the specification teaches the measure of correlation is a percentage match between machine-identified atrial fibrillation events and human assessments of such events, and must therefore be not only a value (because it is compared to a numerical threshold, e.g., 50% in one of the disclosed embodiments) but a calculated value (to determine the percentage match). Finally, Defendants contend the claim language and specification establish that the measure of correlation represents how closely two data sets match because the measure of correlation always results from a comparison of two data sets—i.e., machine-identified arrhythmia events and human assessments of such events—and because some of the claims state the measure of correlation can "indicate[] a high positive predictivity for the identification of atrial fibrillation events," see, e.g., id. col.7 ll.1-2, which, according to the specification, occurs when more than 50% of the machine-identified events "match" humanassessed events, id. col.3 ll.53-57.

Plaintiffs, in contrast, argue the terms "measure" and "correlation" are common terms with plain meanings and the term "measure of correlation" therefore does not require construction. Although their opening memorandum does not elaborate on the plain meaning of these terms, in their responsive memorandum, Plaintiffs maintain the dictionary definitions produced by Defendants support Plaintiffs' contention that the term "measure of correlation" need not be construed. According to these dictionary definitions, a "measure" is a "measured"

quantity" or an "amount" or "degree," and a "correlation" is "a relation existing between phenomena or things or between mathematical or statistical variables which tend to vary, be associated, or occur together in a way not expected on the basis of chance alone." Defs.' Ex. I, ECF No. 59-11. Thus, a "measure of correlation" would refer to the amount or degree of relationship between two things or variables. At the claim construction hearing, Plaintiffs described a "measure of correlation" as a measurement of the relationship between "the machine-identified data and the human assessment." *See* Hr'g Tr. 78, 81, Feb. 20, 2013.

Plaintiffs argue Defendants' proposed construction unduly narrows the plain and ordinary meaning of the term by improperly reading non-limiting characteristics from exemplary embodiments into the claims. Plaintiffs also contend the proposed construction effectively reads limitations that appear in only some claims into all of the claims. In particular, Plaintiffs note that while some claims included a separate limitation directed to "determining at least one measure of correlation" between two groups of "data," i.e., the machine-identified arrhythmia events and human assessments of at least a portion of such events, *see*, *e.g.*, '850 Patent col.6 II.56-57 (emphasis added), the asserted claims do not include this separate determining step and do not refer to the two groups of information to which the measure of correlation relates as "data."

The Court agrees with Plaintiffs that Defendants' proposed construction seeks to limit the term "measure of correlation" based on exemplary embodiments described in the specification. Defendants' proposed construction is based primarily on their contention that the specification defines the measure of correlation as a "percentage match between the human-assessed atrial fibrillation events and the machine-identified atrial fibrillation events." Defs.' Responsive Claim Construction Br. 3. While the specification describes implementations of the invention in which

the measure of correlation is a percentage match between events identified by the processing system and by a cardiovascular technician (CVT), ⁷ the specification does not clearly indicate the patentee intended to define the "measure of correlation" as a percentage match. See Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) ("It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term." (citation omitted)). The specification makes clear the embodiments and implementations disclosed therein are exemplary only and that "other embodiments are within the scope of the [patent's] claims." '850 Patent col.5 Il.50-52; see also, e.g., id. col.2 Il.6-21 (characterizing illustrations, graphs, and diagrams included in specification as depicting "exemplary" embodiments); cf. IP Innovation, L.L.C. v. eCollege.com, 156 F. App'x 317, 321-22 (Fed. Cir. 2005) (construing a claim term as requiring a limitation from an embodiment disclosed in the specification where the patent repeatedly used phrases such as "the present invention" or "the invention of the present disclosure" when describing its inventive features, including the limitation at issue). In addition, the specification and many of the claims themselves refer to the determination of "at least one measure of correlation" between machine-identified arrhythmia events and human assessments of such events. '850 Patent col.4 ll.50-51, col.6, ll.56-57. By requiring the determination of "at least one" measure of correlation, the specification and claims suggest multiple such measures

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⁷ In one implementation of one of the disclosed embodiments, a monitoring system transmits a "flag" if it has identified an atrial fibrillation event in physiological data for a monitored individual in the last ten minutes, and a CVT evaluates a portion of the physiological data and also identifies atrial fibrillation events. A processing system generates a graph related to heart rate trend and atrial fibrillation burden only "if more than 50% of the ten minute flags . . . match events identified by a CVT . . .—a correlation (with respect to the time period at issue) indicating a high positive predictivity for the identification of [atrial fibrillation] events." '850 Patent col.3 ll.47-57. In another embodiment, a processing system determines data is valid if enough of the arrhythmia events identified by a CVT "match" events identified by a monitoring system. *See id.* col.4 ll.52-54.

may be determined, which is consistent with a broad reading of the term. Finally, while the claims of the '850 patent reveal the "measure of correlation" can "indicate[] a high positive predictivity for the identification of atrial fibrillation events during the defined time period," *see*, *e.g.*, *id.* col.7 ll.1-3, the Court is not persuaded this means the "measure of correlation" must in all instances be a percentage match. As Defendants note, in describing an implementation of the invention in which the monitoring system generates a graph only if more than 50% of the atrial fibrillation events "flagged" by the monitoring system match events identified by a CVT, the specification characterizes this 50% match as a "correlation . . . indicating a high positive predictivity for the identification of [atrial fibrillation] events." *Id.* col.3 ll.47-57. Even assuming a "measure of correlation" indicates such a "high positive predictivity" only when there is a percentage match of 50% of more, the requirement that the "measure of correlation" indicate such a high positive predictivity is recited as a limitation in only a handful of dependent claims, most of which depend from independent claims requiring determination of "at least one measure of correlation."

Because the Court finds the intrinsic record does not support the narrow construction of the term "measure of correlation" proposed by Defendants, the Court declines to adopt Defendants' proposed construction. The Court concludes this term does not require construction.

2. "Selectively Presenting the Information Based on a Measure of Correlation"

Asserted claims 1 and 20 of the '850 patent also recite that presenting information regarding heart rate data and duration of atrial fibrillation activity "comprises *selectively* presenting the information based on a measure of correlation between the identified atrial fibrillation events and human-assessments of at least a portion of the identified atrial fibrillation events." '850 Patent col.6 II.15-19 (emphasis added), col.7 II.56-60 (emphasis added). The

parties agree that if the word "selectively" is given its plain and ordinary meaning—i.e., "of, relating to, or characterized by selection," *see* Defs.' Ex. I⁸—the phrase "selectively presenting the information" could refer to selecting *what* information is presented, selecting *how* the information is presented, and/or selecting *whether* information is presented at all. *See* Defs.' Opening Claim Construction Br. 11; Pls.' Responsive Claim Construction Mem. 7.

Defendants concede the claim language does not narrow the meaning of the term "selectively," as used in the '850 patent, but argue the specification reveals that "selectively presenting the information based on a measure of correlation" means "only presenting the information if the measure of correlation has a predefined relationship to a predetermined parameter." Defs.' Opening Claim Construction Br. 11-13. Defendants maintain the specification requires this narrow construction because each of the disclosed embodiments describes a system or procedure in which (1) the measure of correlation controls whether a graph regarding arrhythmia or atrial fibrillation events is generated, and (2) the measure of correlation triggers the generation of a graph only if a high enough proportion of human-assessed events match machine-identified events, i.e., only if the measure of correlation has a predefined relationship (e.g., exceeds, equals, or is less than) to a predefined parameter.

Plaintiffs argue the term "selectively presenting the information based on a measure of correlation" need not be construed, but should instead be understood, consistent with its plain and ordinary meaning, to encompass all types of selecting, without limitation. Plaintiffs concede the specification provides examples of embodiments in which a processing system determines whether or not to present information, but contend the specification reveals that "selectively presenting" also encompasses determining what information to present and how such

⁸ Citations to Defendants' Exhibits are to the exhibits to the Declaration of Christopher H. Blaszkowski accompanying Defendants' opening claim construction brief.

information is presented because it describes different means of pictographically presenting information regarding arrhythmia events. *See*, *e.g.*, '850 Patent fig.2, fig.4, col.4 ll.4-29, col.5 ll.57-61. Plaintiffs also argue Defendants' proposed construction improperly imports limitations expressly recited in other claims into the asserted claims.

Although the phrase "selectively presenting the information based on a measure of correlation" appears in only three independent claims of the '850 patent (asserted claims 1 and 20 and unasserted claim 37), variations of this term appear in numerous other independent and dependent claims. For example, a number of independent claims call for information to be selectively presented, based on a measure of correlation, "if the measure of correlation matches or exceeds at least one predetermined value." E.g., id. col.6 ll.58-61; see also id. col.8 ll.43-46 (same, if the measure of correlation "matches or is less than" at least one predetermined value). These claims expressly recite the same limitations Defendants contend are already included in the definition of "selectively presenting the information based on a measure of correlation," i.e., that information is to be presented if the measure of correlation has a predefined relationship to a predetermined parameter. This suggests that when the patentee wanted to limit selectively presenting information based on a measure of correlation to selecting whether information is presented or to require a particular relationship to a predetermined parameter, he said so. Moreover, adopting Defendants' proposed construction would render the additional limitations regarding selectively presenting and the measure of correlation included in some of the other For example, if "selectively presenting" is limited to independent claims superfluous. determining whether to present information, there would be no reason to use this term in a claim that also specifies information is to be selectively presented "if" the measure of correlation

exceeds a predetermined value. Because Defendants' proposed construction builds into the term "selectively presenting the information based on a measure of correlation" limitations from other independent claims that also use similar terminology, such that the proposed construction would have the effect of rendering the additional limitations superfluous, the Court declines to adopt the proposed construction. *See Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1254 (Fed. Cir. 2011) (declining to construe the term "spring metal adapter" to require a split where some independent claims included additional modifiers consistent with a split, as imposing this limitation would render the additional modifiers superfluous); *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1381 (Fed. Cir. 2006) (recognizing "claim differentiation takes on relevance in the context of a claim construction that would render additional, or different, language in another independent claim superfluous"). The Court agrees with Plaintiffs that the term "selectively presenting the information based on a measure of correlation" does not require construction.

3. "Based on the Human Assessment"

The asserted claims of the '996 patent (independent claims 1, 12, and 23) claim methods, articles, and systems in which information regarding atrial fibrillation events is pictographically

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⁹ That "selectively presenting" information is not necessarily limited to the determination whether to present information at all is underscored by certain dependent claims which further define the term "selectively presenting." For example, claim 11 depends from independent claim 10, which includes the limitation "if the measure of correlation matches or exceeds at least one predetermined value, selectively presenting, based on this measure of correlation, information regarding at least a portion of the arrhythmia events." '850 Patent col.6 ll.58-61. Claim 11 claims the method of claim 10, "wherein identifying arrhythmia events comprises identifying atrial fibrillation events, and selectively presenting information comprises presenting information regarding the atrial fibrillation events and heart rate data for the living being, during a defined time period, together with a common time scale if the measure of correlation indicates a high positive predictivity for the identification of atrial fibrillation events during the defined time period." *Id.* col.6 l.62–col.7 l.3. The claim thus defines "selectively presenting" to encompass what information is presented and how information is presented, in addition to specifying the circumstances in which information will be presented.

presented "based on the human assessment of a subset the identified atrial fibrillation events." For example, independent claim 1 recites:

1. A machine-implemented method comprising:

identifying atrial fibrillation events in physiological data obtained for a living being, wherein identifying atrial fibrillation events comprises examining the physiological data in multiple time intervals, and identifying intervals in which at least one atrial fibrillation event has occurred;

obtaining heart rate data for the living being;

receiving a human assessment of a subset of the identified atrial fibrillation events; and

based on the human assessment of the subset of the identified atrial fibrillation events, pictographically presenting, using a common time scale, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden, wherein pictographically presenting information regarding the heart rate data comprises displaying for each of the multiple time intervals a range of heart rates and a heart rate average.

'996 Patent col.5 1.64–col.6 1.19 (emphasis added).

Defendants argue the phrase "based on the human assessment" should be construed to mean "contingent upon the outcome of the human assessment" because the specification makes clear the outcome of the human assessment controls whether information is pictographically presented. Defs.' Opening Claim Construction Br. 13-14. Plaintiffs argue the plain and ordinary meaning of the term "based on" is broader than Defendants' proposed construction, and also includes concepts such as "taking into account" or "taking into consideration." Plaintiffs contend the term "based on the human assessment" is readily understandable according to its plain and ordinary meaning and need not be construed.

As Defendants note, the specification discloses several exemplary embodiments in which a graph is only generated if a sufficiently high proportion of machine-identified arrhythmia

events are validated by a CVT reviewing physiological data about such events. See, e.g., '850 Patent col.1 ll.62-65 ("In one implementation, the graph only displays events where [atrial fibrillation] detection is validated by a technician finding [atrial fibrillation] in over 50% of the automatically identified events."); col.3 ll.47-57 (describing an implementation in which a processing system only generates a graph if more than 50% of machine-identified events match events identified by a CVT). The specification makes clear the disclosed embodiments are exemplary only. There is no indication the patentee intended the claims to be limited to the disclosed embodiments; to the contrary, the specification expressly states "other embodiments are within the scope of the . . . claims." *Id.* col.5 ll.50-52. Moreover, while Defendants argue the claims of the '996 patent confirm that the invention of the patent "is concerned with 'pictographically presenting' only data that a technician determines to be valid," Defs.' Opening Claim Construction Mem. 15, the claims refute this contention, as limitations specifically directed to determining that atrial fibrillation events are valid and pictographically presenting information based on the determining are included in only certain dependent claims. ¹⁰ In these circumstances, Defendants' proposed construction represents an attempt to improperly limit the claims based on exemplary embodiments. The Court therefore finds the term "based on the human assessment" need not be construed.

4. "Subset"

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¹⁰ For example, claim 2 depends from asserted independent claim 1 and claims the method of claim 1 "further comprising determining that the identified atrial fibrillation events are valid when a threshold percentage of the identified atrial fibrillation events match events identified by the human assessment; and wherein pictographically presenting based on the human assessment comprises pictographically presenting based on the determining." '996 Patent col.6 Il.20-29. The inclusion of these limitations in claim 2 gives rise to a presumption they are not present in claim 1. *See Phillips*, 415 F.3d at 1315.

The term "subset" appears in asserted claims 1, 12, and 23 of the '996 patent, all of which require a human assessment of a subset of machine-identified atrial fibrillation events. The parties disagree as to whether a subset may include all elements of the set from which it is derived. Plaintiffs argue the term "subset" should be construed to mean "a set consisting of elements of a given set that can be the same as the given set or smaller." Pls.' Opening Claim Construction Mem. 14. Defendants contend the term should be construed to mean "less than all (i.e. no more than a proper subset)." Defs.' Opening Claim Construction Br. 15.

Plaintiffs' proposed construction is consistent with the meaning of the term "subset" as used in mathematics. See Pls.' Ex. 6^{11} ("A subset A of a set B is a set all of whose elements are included in B."); Pls.' Ex. 7 (defining a subset as "[a] set contained within a set"). In mathematical usage, a subset that does not include all elements of the set to which it relates is a "proper subset." See Pl.'s Ex. 6 ("A set X is a proper subset of a set Y if there is an element of Y which is not in X while X is a subset of Y."). A subset that includes all members of the original set is an "improper subset." Milo Decl. \P 26. Plaintiffs argue the intrinsic evidence provides no explicit definition for the term "subset"; hence, because the claims refer to a "subset" rather than a "proper subset," the term should be construed to include both proper and improper subsets.

Defendants argue the intrinsic record supports construing the term "subset" more narrowly as limited to a proper subset. The Court agrees. The claims of the '996 patent themselves do not suggest a meaning for the term "subset." The specification, however, reveals that the patentee used the term "subset" to refer to fewer than all of the identified atrial fibrillation events. The term "subset" appears only twice in the specification, both times in the

¹¹ Citations to Plaintiffs' Exhibits are to the exhibits to the Declaration of Alexandra O. Fellowes accompanying Plaintiffs' opening claim construction memorandum.

description of the same exemplary embodiment. In that embodiment, a monitoring system identifies arrhythmia events in physiological data and reports physiological data for a subset of the identified events to a processing system. "Notably, the system, in this implementation, need not report physiological data for each flag assigned at 503, but need only report data associated with the most significant events at 502, thereby minimizing the data sent to a CVT." '850 Patent col.4 ll.41-45. The CVT analyzes the data and reports whether arrhythmia events have occurred; the processing system determines at least one measure of correlation between the two data sets (i.e., machine-identified and human-assessed events); and, if enough of the human-assessed events match machine-identified events, the system determines the data is valid and the data associated with the machine-identified events is pictographically presented. "Significantly, in this implementation, while this pictographic representation can contain all such data, the CVT need only review a subset of this data," with the result that "the system achieves increased accuracy in the presentation of information relating to arrhythmia events while minimizing the data that the CVT reviews." *Id.* col.4 ll.58-64.

Plaintiffs argue this discussion does not support Defendants' proposed construction because the specification merely provides that the system "need not report" all event data to the CVT and "need only report" the most significant events, but does not prohibit reporting of all events. These references, by themselves, may not limit the term subset to a proper subset since they permit, but do not require, that data for fewer than all events be transmitted. However, the specification goes on to state that while the pictographic representation generated may contain data regarding all of the machine-identified events, the CVT "need *only* review a subset" of the data. *Id.* col.4 ll.60-61 (emphasis added). This later reference makes clear that the subset must

include less than all of the event data, for if the subset could include all events, it would make no sense to refer to the CVT as needing to "only review a subset." *Id.* (emphasis added).

The claims of the related '850 patent also provide some support for Defendants' proposed construction. As Defendants note, claim 43 of the '850 patent claims a machine-implemented method comprising several steps, including "receiving a second group of data that includes human assessments of *at least a portion* of the arrhythmia events." '850 Patent col.12 Il.33-35 (emphasis added). Claim 44, which depends from claim 43, claims "[t]he method of claim 43, wherein receiving human assessments comprises receiving human assessments of a *subset* of the identified arrhythmia events" *Id.* col.12 Il.49-51 (emphasis added). The fact the dependent claim specifically redefines "receiving human assessments" as receiving human assessments of a "subset" of the identified arrhythmia events, rather than "at least a portion" of such events, gives rise to a presumption that the two terms have different meanings. *See Phillips*, 415 F.3d at 1315 ("[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim."). Because "at least a portion" could include the whole, the use of the word "subset" in the dependent claim suggests "subset" means less than all.

Because the intrinsic evidence is consistent with Defendants' proposed construction, the Court will construe the term "subset" to mean "less than all (i.e., no more than a proper subset)."

B. The '095 Patent

The '095 patent, entitled "Adaptive Selection of a Warning Limit in Patient Monitoring," relates to "the monitoring of a physiological characteristic of a patient, and, more particularly, to establishing a warning limit that may be used to indicate a variation of the physiological characteristic that necessitates immediate attention." '095 Patent col.1 ll.4-8. For example, a

warning limit for the physiological characteristic of a heartbeat may relate to, *inter alia*, the frequency of heartbeats, the shape of a particular part of the heartbeat waveform, or the amplitude of a particular part of the heartbeat signal, and may include a minimum or maximum value of these features. *See id.* col.2 ll.17-18, col.4 ll.14-25. Although warning limits may be established based on textbook descriptions of physiological characteristics, in practice, the appropriate warning limit may vary from patient to patient depending on factors such as variations in sensor performance, individual human characteristics and responses, and personal experiences. *See id.* col.1 ll.40-48. The invention of the '095 patent fills a need to "to establish realistic warning limits characteristic of situations that are truly urgent" by providing "a technique for monitoring a patient in which one or more warning limits are recursively reevaluated as necessary," so as to "discover[] which warning limits are most meaningful for the individual patient," thereby increasing "the precision of the generation of warnings" and avoiding unnecessary urgent communications. *See id.* col.1 ll.54-67, col.2 ll.2-3, 62-65.

In general, the claims of the '095 patent are directed to a method of monitoring a patient that includes establishing a current warning limit for a physiological characteristic of the patient; providing a sensor for the physiological characteristic; measuring a measured value of the physiological characteristic using the sensor; comparing the measured value and the current warning limit; generating a warning signal if the measured value is outside the current warning limit; and selecting a revised warning limit responsive to at least one of the earlier steps. *See id.* col.1 ll.14-31.

1. "Selecting [a Revised Warning Limit]"

Asserted claims 1 and 11 of the '095 patent recite that the claimed method of patient monitoring includes the step of "selecting a revised warning limit" responsive to at least one of a

number of other enumerated steps. *Id.* col.6 ll.66-67, col.8 ll.3-7. The parties dispute whether this "selecting" step must be performed by a processor or, alternatively, can be performed by either by a processor or a human being. Defendants argue the claims and specification reveal the selecting step must be performed by a processor and the term "selecting [a revised warning limit]" should therefore be construed to mean "selecting by a processor [a revised warning limit]." Defs.' Opening Claim Construction Br. 17. Plaintiffs, in contrast, maintain the claims and specification make clear the selecting step can be performed not only by a processor but also by a human. Plaintiffs further contend the ordinary meaning of the word "selecting" is broad enough to encompass both methods and, as a result, the Court need not construe this term.

The opening paragraph of the "summary of the invention" section creates ambiguity as to how the selecting step is performed. The summary states, at the outset, that "[p]roposed changes to the warning limits are made without human intervention, but in some cases the proposed changes may be reviewed by a human being to be certain that they are realistic." *Id.* col.2 ll.4-7. Defendants argue this statement outlines two scenarios for the selection of a revised warning limit: one in which the revised warning limit is selected by a processor without human review and another in which the revised warning limit is selected by a processor and then reviewed by a human being. Because in both scenarios the selection is made by a processor, Defendants contend the specification reveals the selection must always be made by a processor. In the next sentence, however, the summary states the approach of the '095 patent "is fully compatible with adjustments to warning limits made by medical personnel," *id.* col.2 ll.7-9, suggesting a revised warning limit may, at least in some instances, be selected by a human being.

The specification elsewhere makes clear that while the step of selecting a revised warning limit is preferably performed without human intervention, it does not exclude such intervention. The summary, for example, goes on to describe the selecting step as follows:

The method includes selecting a revised warning limit responsive to at least one of the steps of providing and measuring, preferably without human intervention (i.e., automatically). However, a human being may review the revised warning limit. That is, the automated system may propose the revision, subject to revision by the human being.

Id. col.2 ll.24-30. The summary thus reflects that the selecting step is preferably, though not necessarily, performed by a processor, and that the revised warning limit selected at the selecting step is subject to review (and revision) by a human being.

The detailed description echoes this point, explaining, in describing the preferred embodiment of the invention, "[t]o improve the efficiency of the system, revised warning limits are selected, preferably but not necessarily without human intervention (i.e., 'automatically')." *Id.* col.5 ll.28-30. The description goes on to provide examples of circumstances in which review of a revised warning limit is and is not required, specifying that changes that is "more closely associated with . . . medical condition[s] [are] more likely to require a medical review." *Id.* col.5 ll.41-43. The description states, for example,

if a heartbeat frequency warning limit of 100 beats per minute is to be changed to 120 beats per minute based on extended experience in order to obtain a better indicator of when urgent communication is required, it is preferred that the central processing unit 60 of the central unit 54 make a recommendation based upon data analysis and without human intervention, and then a human being in the form of the patient's doctor or a medical technician approve the change under the human review 66.

Id. col.5 ll.43-51. Although Defendants characterize this example as one wherein the revised warning limit is selected by a processor, by suggesting it is *preferred* that the revised warning

limit be recommended by a processor without human intervention, the example supports Plaintiffs' position that the selecting step does not exclude human intervention.

Defendants argue the preferred embodiment shows the revised warning limit must be selected by a processor because the diagram depicting the embodiment characterizes the selecting step (step 40) as "select revised warning limit without human intervention," and then shows a further "human review" step which is "optional" (step 42). *See id.* fig.1. As noted, however, the text accompanying the diagram states the selecting step depicted in step 40 is performed "preferably but not necessarily without human intervention," *id.* col.5 ll.29-30, suggesting step 40 depicts the preferred, not the required, method of selection.

The claims of the '095 patent also support Plaintiffs' position that the selecting step is not limited to selection performed by a processor. Independent claim 1, for example, claims a method of monitoring a patient which includes, as its final step, "selecting a revised warning limit responsive to at least one of the steps of providing and measuring." *Id.* col.6 ll.66-67. Claim 10, which depends from claim 1, claims "[t]he method of claim 1, wherein the step of selecting is performed without human intervention." *Id.* col.7 ll.33-34. By adding to the method in claim 1 the limitation that the selecting step be performed "without human intervention," claim 10 gives rise to a presumption that claim 1 should not be construed as requiring this limitation, i.e., that the selecting step described in claim 1 does not exclude human involvement. See Phillips, 415 F.3d at 1315.

¹² Claims 16 and 18, which depend from independent claims 11 and 17, respectively, add to those independent claims the same limitation that the selecting step be performed "without human intervention," and thus give rise to the same presumption that the selecting step of the method claimed in the independent claims is not required to be performed without human intervention.

Defendants argue claim 10 merely reflects the scenario in which a revised warning limit is selected by a processor without human review, such that human intervention in the selecting step described in claim 1 could consist of human review. However, claim 2, which also depends from claim 1, claims "[t]he method of claim 1, including an additional step, after the step of selecting, of a human being reviewing the revised warning limit," *id.* col.7 ll.1-3, thereby suggesting that "reviewing" a revised warning limit is a separate step from "selecting" the limit. Claim 10 relates only to the selecting step; hence, it cannot properly be read as covering performing the selecting step without optional human review.

Because the intrinsic record does not require that the selecting step in the method of the '095 patent be performed by a processor, the Court declines to adopt Defendants' proposed construction of the term "selecting" as meaning "selecting by a processor." Moreover, because the ordinary meaning of the term "selecting" is broad enough to encompass selecting with or without human intervention, the Court finds no construction of the term "selecting" is necessary.

2. "Physiological Characteristic" and "Measured Value [of the Physiological Characteristic]"

The terms "physiological characteristic" and "measured value [of the physiological characteristic" appear in asserted independent claims 1 and 11 of the '095 patent, both of which claim a method of monitoring a patient that includes, *inter alia*, the steps of "establishing a current warning limit for a physiological characteristic of the patient," "providing a sensor for the physiological characteristic," and "measuring a measured value of the physiological characteristic of the patient using the sensor." '095 Patent col.6 II.57-62, col.7 II.43-48. This measured value is then compared to the current warning limit to determine whether to generate a

warning signal.¹³ *Id.* col.6 ll.63-65, col.7 l.49–col.8 l.2. The parties disagree as to whether these terms require construction and how they should be construed.

Plaintiffs argue the term "physiological characteristic" should be construed to mean "a physiological state measurable using a sensor, such as heartbeat rate, respiration rate, blood pressure, and the like." Pls.' Opening Claim Construction Mem. 18. Plaintiffs further argue that if their proposed construction of "physiological characteristic" is adopted, the term "measured value [of the physiological characteristic of the patient]" need not be construed, but should be given its plain and ordinary meaning as the result of the step of measuring, i.e., the value that is measured using the sensor.

Defendants argue the term "physiological characteristic" need not be construed because it has a plain and ordinary meaning and nothing in the patent suggests the term was intended to have a different meaning. Starting with the proposition that "physiology" refers to the study of the function of living organisms, Defendants argue the plain and ordinary meaning of the term "physiological characteristic" is a characteristic or feature that relates to the function of a living organism. *See* Defs.' Ex. J. Defendants thus argue that if the term is construed, it should be construed to mean "a feature relating to a function of a living organism." Defs.' Opening Claim Construction Br. 20. Defendants dispute that the '095 patent requires a "physiological characteristic" to be measurable using a sensor, noting the claims recite the step of "measuring a *measured value* of the physiological characteristic . . . using the sensor," '095 Patent col.6 ll.61-62 (emphasis added), rather than measuring the physiological characteristic itself. Defendants further argue the specification reveals the "measured value" of the physiological characteristic

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¹³ The term "physiological characteristic" also appears in asserted dependent claim 9 of the '095 patent. *See* '095 Patent col.7 ll.31-32 (claiming the method of claim 1 "wherein the physiological characteristic is a characteristic of the heart").

that is measured using the sensor is the output of the sensor, from which the physiological characteristic is then calculated. Defendants therefore maintain the term "measured value [of the physiological characteristic of the patient]" should be construed to mean "output of the sensor [of the physiological characteristic of the patient]." Defs.' Opening Claim Construction Br. 21.

As Defendants note, in describing the preferred embodiment of the invention, the specification provides a more detailed description of how a measured value of a physiological characteristic is measured using a sensor. The specification explains a sensor is typically in contact with the patient and in communication with a central processing unit of a remote monitoring unit. *See* '095 Patent col.3 II.33-35, 46-48. The sensor obtains data relating to the physiological condition at issue from the patient and communicates this data output to the central processing unit. *See id.* col.4 II.29-34. For example, in the case of a heartbeat sensor, "the data output is a series of data pairs of sensor voltage output as a function of time." *See id.* col.4 II.31-34. The sensor signal is then interpreted, which involves "extract[ing] the type of information of interest from the sensor signal" (e.g., the frequency of heartbeats) and determining a measured value of the information of interest. *Id.* col.4 II.50-53, 60.

Defendants argue because the specification reveals that what is actually measured by the sensor is (in the case of a heartbeat sensor) a voltage output from which a heart rate must then be calculated, the term "measured value" refers to the output of the sensor (e.g., the voltage output) rather than to the value derived from interpreting that output (e.g., the heartbeat rate). Although the Court agrees the specification makes clear that sensor output requires interpretation to produce the desired measure of the physiological characteristic of interest, the Court finds Defendants' proposed construction is inconsistent with the way the term "measured value of the physiological characteristic of the patient" is used in the claims.

In addition to reciting a measuring step, consisting of "measuring a measured value of the physiological characteristic of the patient using the sensor," the asserted independent claims recite a comparing step, which involves "comparing the measured value and the current warning limit." Id. col.6 ll.61-64, col.7 ll.47-50. These claims also recited a "generating" step, consisting of "generating a warning signal responsive to the step of comparing." Id. col.6 ll.64-65, col.8 ll.1-2.14 According to the specification, the warning limit is not expressed in terms of sensor output but as a type of information that can be determined from the sensor output, such as (in the case of a heart sensor) a maximum or minimum number of heartbeats per minute. See id. col.4 II.12-25 (observing "in the case of a heart sensor that measures a voltage as a function of time, for example, the warning limit may relate to any of a wide variety of types of information that may be determined from the heart sensor output to the central processing unit"). Thus, because the measured value of the physiological characteristic must be compared with the warning limit to determine whether to generate a warning signal, it follows that the measured value is not the raw data (or voltage output) generated by the sensor but the interpreted value of such data. See col.5 11.5-9 (noting "if the heartbeat exceeds a heartbeat warning limit value and the blood oxygen saturation level also exceeds a blood oxygen warning limit value, then an urgent communication may be called for").

Although Defendants argue the phrase "measuring a measured value" is vague and confusing, Defendants' proposed construction is inconsistent with the claims and specification, and the Court therefore declines to adopt it. The Court agrees with Plaintiffs that a person of ordinary skill in the art would understand the "measured value" of a physiological characteristic of a patient to be the result of the step of measuring. The Court therefore finds the term

¹⁴ In claim 1, the generating step is claimed as part of the comparing step. *Id.* col.6 ll.63-65.

"measured value [of the physiological characteristic of the patient]" does not require construction.

As for the term "physiological characteristic," the parties agree their main dispute concerns whether a physiological characteristic must be measurable using a sensor. Defendants argue imposing such a limitation is inconsistent with the measuring step of the asserted claims, which involves "measuring a measured value of the physiological characteristic of the patient using the sensor." E.g., id. col. 6. ll.61-62. Having rejected Defendants' proposed construction of the term "measured value" as meaning "output of the sensor," the Court also disagrees with Defendants that a physiological condition need not be measurable using a sensor. Even if the sensor output (e.g., voltage) must be interpreted before a measured value of the physiological characteristic (e.g., heartbeat rate) may be determined, the measured value is still measured using the sensor. The specification reinforces this point, stating "[t]he physiological characteristics of the patient are measured using the sensor." Id. col.4 11.29-30. The Court agrees with Defendants, however, that the term "physiological characteristic" does not otherwise require construction, and Plaintiffs have not explained why it is necessary to provide examples of specific physiological characteristics. Accordingly, to resolve the parties' dispute, the Court will construe the term "physiological characteristic" to mean "a physiological characteristic measurable using a sensor."

C. The '237 Patent

The '237 patent, entitled "Biological Signal Management," discloses systems and techniques for managing biological signals. The specification explains biological signals are electrical or optical streams that, in the medical context, include information relating to the physiological state of an organism which can be used to diagnose and treat disease. *See* '237

Patent col.1 ll.7-12. The claims of the patent are directed to methods and articles for monitoring a cardiac biological signal using electrocardiographic monitoring instrumentation. Broadly speaking, the claimed method involves receiving a cardiac biological signal that includes events relating to a medical purpose; determining a measure of merit for each identified event; comparing the measure of merit to a merit criterion; transmitting information regarding a subset of the events meeting the merit criterion to a remote medical receiver; and discarding information regarding the events that do not meet the merit criterion. The claimed methods aim to increase the average relevance of data transmitted for review by medical personnel so as to minimize data handling costs while also ensuring relevant data is not lost.

1. "Measure of Merit"

Each of the independent claims of the '237 patent includes a step requiring the determination of a "measure of merit" of each identified cardiac event. The parties offer competing constructions of the term "measure of merit." Plaintiffs argue the term should be construed to mean "valuation applied to a particular purpose." Pls.' Opening Claim Construction Mem. 21. Defendants contend the term should be construed to mean "a single grade for an event based on both a grading of a severity of the cardiac condition associated with the event and a grading of the noise in the information describing the event." Defs.' Opening Claim Construction Br. 26.

Plaintiffs derive their proposed construction directly from the specification, which states "[a] measure of the merit of an event is a valuation of an event when applied to a particular purpose." '237 Patent col.8 ll.44-46. The specification goes on to provide an example, noting "when the biological signal is monitored for diagnostic medical purposes, the measure of the merit of an event can describe the diagnostic value of the information content of the event." *Id.*

col.8 ll.46-49. Plaintiffs argue because the patentee acted as his own lexicographer by expressly defining the term "measure of merit" in the specification, the patentee's definition controls.

Defendants acknowledge the specification includes Plaintiffs' proposed definition, but argue this construction is ambiguous and ignores claim language that further limits the meaning of the term. All of the independent claims of the '237 patent specify that the measure of merit must embody both "a severity of the cardiac condition associated with the event and an amount of noise in the information describing the event." *Id.* col.15 ll.27-30, col.17 ll.17-20, col.17 ll.56-59, col.19 ll.5-8. Defendants argue this claim language, some of which was added during the prosecution of the patent, hakes clear that the term "merit" embodies both severity and noise associated with cardiac event information, but does not explain how the measure of merit embodies these two factors or the form the measure of merit must take. Defendants argue these questions are answered by Table 4 in the specification, which shows an approach for determining a measure of merit whereby an event is assigned a "discrete merit grade[]" ("lowest," "low," "medium," or "high") based on the grades assigned for the severity and noise of the event. '237

¹⁵ The wording of this limitation varies slightly from claim to claim. *Compare, e.g.*, '237 Patent col.15 ll.27-30 (stating the measure of merit "embodies a severity of the cardiac condition *associated with the event* and an amount of noise in the information describing the event" (emphasis added)), *with id.* col.17 ll.17-20 (stating the measure of merit "embodies *both* the severity of the cardiac condition *indicated by the information describing the event* and an amount of noise in the information describing the event" (emphasis added)).

¹⁶ Defendants note independent claim 13 of the '237 patent (which eventually issued in its revised form as claim 1) originally recited "a merit of each event based on one or more of a severity of a cardiac condition associated with the event and *a quality* of the event." Defs.' Responsive Claim Construction Br. 24 (emphasis added) (quoting Original Specification of U.S. Patent Application No. 10/770,702, at p. 21). Through a series of amendments, however, the patentee limited the scope of the claim to its current form, i.e., "determining a measure of merit of the information describing each event, wherein the measure of merit embodies a severity of the cardiac condition associated with the event and an amount of noise in the information describing the event." '237 Patent col.15 ll.26-30.

Patent col.10 II.41-62.¹⁷ Defendants argue the term "measure of merit" should be construed based on the process described in Table 4 because it is the only process for determining a measure of merit disclosed in the specification that corresponds to the definition of "merit" in the claims, and because the patentee limited himself to this embodiment during prosecution of the patent.

The Court agrees with Plaintiffs that Defendants' proposed construction unduly narrows the term "measure of merit" based on a single embodiment. Although the prosecution history reveals the patentee narrowed the scope of what the measure of merit must represent, this narrowing is part of the claims themselves, which expressly require that the measure of merit embody both "a severity of the cardiac condition associated with the event and an amount of noise in the information describing the event." *See, e.g., id.* col.15 Il.28-30. Because all of the independent claims specifically recite these limitations, the Court perceives no reason to incorporate them into the definition of "measure of merit." *See Woods v. DeAngelo Marine Exhaust, Inc.*, 692 F.3d 1272, 1285 (Fed. Cir. 2012) (finding it unnecessary to read proposed limitation into claim term where every claim that used the term already included the limitation).

In addition, the claims do not require severity and noise to be graded. While the specification describes different ways in which the severity and quality of an event can be determined or "graded," it also makes clear "[t]he measure of the merit can be determined using any of a number of different approaches." '237 Patent col.10 II.57-58. The claims underscore this point, as several dependent claims include limitations as to how the measure of merit is to be

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¹⁷ Table 4 includes three columns, the first headed "Severity," the second headed "Noise," and the third headed "Quality." *Id.* col.10 ll.41-51. The text accompanying the Table explains the "Quality" column shows "examples of various discrete merit grades (lowest, low, medium, and high) that can be assigned to an event when an event is determined to have the corresponding severity and quality." *Id.* col.10 ll.59-62. For example, the first row of the Table shows a Severity rating of "Low," a Noise rating of "High," and a Quality rating of "Lowest."

determined. *See*, *e.g.*, *id.* col.17 ll.33-36 (claiming "[t]he method of claim 22, wherein determining the measure of merit of the information describing each event comprises determining the amount of noise in the information describing the event"); *id.* col.17 ll.37-29 (claiming "[t]he method of claim 22, wherein determining the measure of merit of the information describing each event comprises determining a signal dropout during the event"). The Court therefore finds Defendants' proposed construction is unwarranted insofar as it specifies that the measure of merit is to be determined "based on both a grading of severity of the cardiac condition associated with the event and a grading of the noise in the information describing the event."

The remaining dispute between the parties is whether the "measure of merit" of an event is a "valuation [of the event] when applied to a particular purpose" or a "single grade for [the] event." The claims reveal the measure of merit must be compared with a "merit criterion" so a determination can be made whether the measure of merit "meets" or "fail[s] to meet" the "merit criterion," or whether the measure of merit is "among a certain number of the most meritorious." See, e.g., id. col.15 ll.31-62, col.16 ll.2-3. The specification confirms the measure of merit is capable of being ranked. See, e.g., id. col.8 ll.55-59 (noting a determination can be made whether a measure of merit of an event "is greater than the measure of merit of the least meritorious event of the same category currently associated with the time span that includes the identified event" (emphasis added)). Nothing about these requirements—i.e., that the measure of merit must be capable of being compared and ranked—suggests the measure of merit must be a "grade," as opposed to a "valuation." Moreover, while the specification indicates the measure of merit "can be graded on a discrete scale or on a continuous scale," it also states the measure "can be determined using any of a number of different approaches." Id. col.10 ll.55-58 (emphasis

added). The Court therefore perceives no reason to deviate from the specification's express definition of a "measure of merit" as a "valuation" of an event. *See, e.g., Phillips*, 415 F.3d at 1316 (holding where the specification "reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor's lexicography governs"). Accordingly, the Court will construe the term "measure of merit" to mean "a valuation applied to a particular purpose."

2. "Discarding [Information]"

The term "discarding" also appears in all independent claims of the '237 patent, each of which includes at least one "transmitting" step and at least one "discarding" step. At the transmitting step, information describing a subset of events for which the measure of merit meets a merit criterion is transmitted to a remote medical receiver. At the discarding step, information describing a subset of events for which the measure of merit fails to meet the merit criterion are discarded. Defendants assert—and Plaintiff do not dispute—the plain and ordinary meaning of the word "discard" is "to get rid of" or "to remove." Defs.' Ex. I. Defendants argue that, consistent with this plain and ordinary meaning, the term "discarding [information]" should be construed to mean "not storing [information] or erasing [information]." Defs.' Opening Claim Construction Br. 28. Plaintiffs contend that in the context of the '237 patent, the term should be construed to mean "not transmitting [information] from the electrocardiographic monitoring instrumentation to the remote medical receiver." Pls.' Opening Claim Construction Mem.

¹⁸ Defendants initially proposed that the term "discarding [information]" be construed to mean "not storing [information]." After submission of Plaintiffs' opening claim construction memorandum, and in an effort to address the issues Plaintiffs raised therein, Defendants modified their proposed construction to include "not storing [information] *or erasing [information]*." *See* Defs.' Responsive Claim Construction Br. 26-27 & n.19.

The ordinary meaning of the term "discarding" favors Defendants' proposed construction. Having used the word "transmitting" to describe what is done with the information describing a subset of events that meet the merit criterion, the patentee could have specified that information describing a subset of events that do not meet the merit criterion is "not transmitted" if that is what the patentee intended to convey. Instead, the patentee used the stronger term "discarding," which connotes getting rid of the information.

Defendants' proposed construction is also consistent with the examples of discarding information the patentee cited to the patent examiner during prosecution of the '237 patent. Seeking to overcome a rejection of certain claims as anticipated by U.S. Patent No. 7,732,708 (hereinafter the "Nau patent"), the patentee argued the Nau patent did not describe classifying events into two different categories and then, for each category, transmitting information describing a subset of events with merits meeting a merit criterion and discarding a subset of events with merits that do not meet the merit criterion. The patentee acknowledged Nau "describe[d] two situations in which information is discarded," but distinguished both situations in part on the basis that there was "no description or suggestion that information describing subsets of the events classified in two categories is both transmitted and discarded," as recited in the rejected claims. Defs.' Ex. K at 12-13. Notably, the two situations described in the Nau patent which the patentee explicitly characterized as involving information being discarded include one in which data is written over when the capacity of the data record is filled, Defs.' Ex. L, Nau Patent col.10 ll.65-67, and another in which data is "not permanently stored in the current ... data record," id. col.9 ll.58-59. See Defs.' Ex. K at 12. The patentee's recognition that

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¹⁹ The second example of discarding in the Nau patent addressed by the patentee derives from a portion of specification which describes that

writing over data (a means of erasing data) and not permanently storing data are examples of "discarding" information supports Defendants' proposed construction.

Plaintiffs argue Defendants' proposed construction of "discarding" as "not storing" is inconsistent with the specification because the specification describes embodiments in which discarded events are stored, at least temporarily. In particular, the specification includes embodiments in which events that are ultimately discarded are part of a "data structure." According to Plaintiffs' expert, Ted Milo, a person of ordinary skill in the art would understand the references in the specification to "data structure[s]" as inherently requiring that the structures be stored, at least temporarily, in memory. Milo Decl. ¶ 62. Plaintiffs thus contend that because some of the disclosed embodiments reflect that in some instances discarded events are stored, at least temporarily, as part of a data structure, the term "discarding" cannot mean "not storing." 20

if an arrhythmic event is detected and initially diagnosed as an incipient arrhythmic episode, but a return to sinus (normal) rhythm is detected before any therapy is delivered (i.e., therapy is not initiated or is terminated), then the [electrogram (EGM)] data corresponding to this event will be discarded (i.e., not permanently stored in the current EGM data record), but the diagnostic data corresponding to this event may be permanently stored in the current diagnostic record.

Defs.' Ex. L, Nau patent col.9 ll.53-61. Plaintiffs argue this passage reveals that, even in the context of the Nau patent, the term discarding does not mean not storing because while the EGM data corresponding to an event is not permanently stored, the diagnostic data associated with the event may be permanently stored. The fact that the diagnostic data may be permanently stored does not affect the meaning of the term "discarded," however, as the patent does not describe the diagnostic data as being discarded. Rather, the patent describes only the EGM data as discarded and explains discarded means not permanently stored in the current EGM data record.

²⁰ In one embodiment, for example, a subset of events in a given time span are associated with the time span through a process that involves allocating the meritorious events to a data structure. *See* '237 Patent fig. 9, col.8 ll.21-23. The measure of merit of an identified event is compared to the measure of merit of the least meritorious event currently associated with the same time span. If the identified event is not as meritorious as the least meritorious event associated with the time span, the identified event is discarded. If, however, the identified event is more meritorious than the least meritorious event, the least meritorious event is discarded and the identified event is

Plaintiffs also argue Defendants' proposed construction is inconsistent with the intrinsic record to the extent Defendants construe "discarding" to mean "erasing" because erasing requires the affirmative step of clearing the memory locations in which the information is stored, which is not reflected anywhere in the patent.

Even if events may be stored temporarily while they are being processed and analyzed for purposes of determining which subset of events will be transmitted to the remote medical receiver and which subset will be discarded, Plaintiffs offer no evidence that the discarded events are stored permanently in memory. Moreover, while Plaintiffs contend the intrinsic record does not reflect that events are erased, the use of the term "discarding," which has an ordinary meaning of getting rid of, and the patentee's concession during prosecution that writing over data is an example of discarding, conveys that discarded events may include events that are erased.

Finally, the Court agrees with Defendants that construing the term "discarding" to mean "not transmitting" effectively renders the "discarding" step in the claims superfluous. By specifying that the transmitting step involves transmitting information describing a subset of events for which the measure of merit meets a merit criterion, the claims implicitly suggest that information describing events with merits that do not meet the merit criterion are not transmitted. Because the transmitting step already conveys that the latter subset of events is not transmitted, "discarding" must mean something other than "not transmitting" for the discarding step to have any real meaning. See Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game Tech., 709 F.3d 1348,

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associated with the time span. Because, in the latter situation, the discarded least meritorious event was previously associated with the time span via a data structure—and was therefore stored, at least temporarily, in memory—Plaintiffs argue this embodiment includes an example of a discarded event that is also stored. Plaintiffs also point to the embodiment reflected in figure 11, which describes a data structure that includes a data assembly, a series of associated events (i.e., events allocated to time spans), and a series of discarded events, which are not associated with time spans. *See id.* fig.11, col.11 ll.12-17, 50-52. Plaintiffs argue because the discarded events are part of the data structure, they must have been stored, at least temporarily, in memory.

1357-58 (Fed. Cir. 2013) (rejecting proposed construction of the step of "awarding" a prize that would render the prior step of "identifying" a prize superfluous).

For the foregoing reasons, the Court will adopt Defendants' proposed construction for the term "discarding [information]" and will construe the term to mean "not permanently storing [information] or erasing [information]."

D. The '207 Patent

The '207 patent, entitled "Cardiac Monitoring," claims devices, methods, and articles for monitoring cardiac activity and, in particular, for collecting information describing the variability in heart rate over a series of beats and determining whether the variability is indicative of atrial fibrillation and/or atrial flutter. Both of the disputed claim terms from the '207 patent—"ventricular beat detector" and "in light of the variability in the beat-to-beat timing caused by the ventricular beats"—appear in independent claim 1, which claims:

1. A device, comprising:

- a beat detector to identify a beat-to-beat timing of cardiac activity;
- a ventricular beat detector to identify ventricular beats in the cardiac activity;
- variability determination logic to determine a variability in the beat-tobeat timing of a collection of beats;
- relevance determination logic to identify a relevance of the variability in the beat-to-beat timing to at least one of atrial fibrillation and atrial flutter; and
- an event generator to generate an event when the variability in the beat-tobeat timing is identified as relevant to the at least one of atrial fibrillation and atrial flutter in light of the variability in the beat-tobeat timing caused by ventricular beats identified by the ventricular beat detector.

'207 Patent col.12 ll.12-27 (emphasis added).

1. "Ventricular Beat Detector"

As noted, the device claimed in claim 1 of the '207 patent includes a "ventricular beat detector" that identifies ventricular beats in cardiac activity. The parties agree the specification

defines the term "ventricular beats" to mean "premature ventricular beats that are irregular beats that interrupt the normal heart rhythm." See Joint Claim Construction Statement 6, ECF No. 51; see also '207 Patent col.9 11.10-12 ("Ventricular beats (i.e., premature ventricular beats) are irregular beats that interrupt the normal heart rhythm."). The same portion of the specification from which the parties derived their agreed joint construction for "ventricular beats" states a "[v]entricular beat detector 810 is a device such as a circuit or other arrangement that identifies ventricular beats." '207 Patent col.9 ll.9-10. Based on this language and language elsewhere in the specification suggesting the ventricular beat detector can be hardware and/or software running on a processor, see id. col.11 ll.5-30, Plaintiffs argue the term "ventricular beat detector" should be construed to mean "hardware and/or software running on a processor that identifies ventricular beats." Pl.'s Opening Claim Construction Mem. 26. Defendants argue the term should be construed as Plaintiffs propose with one additional limitation—that the ventricular beat detector identify ventricular beats "as distinct from other regular or irregular beats" or, alternatively, that it identify "only ventricular beats." Defs.' Responsive Claim Construction Br. 19.

Defendants argue this additional limitation is required by claim language and language in the specification regarding the relevance of ventricular beats to determining whether variability in the beat-to-beat timing is indicative of atrial fibrillation or atrial flutter. Claim 1 specifies an event generator will "generate an event when the variability in the beat-to-beat timing is identified as relevant to at least one of atrial fibrillation and atrial flutter in light of the variability

²¹ Defendants originally proposed that the term "ventricular beat detector" be construed to mean "hardware, and/or software running on a processor, that identifies ventricular beats as distinct from other regular or irregular beats." Defs.' Opening Claim Construction Br. 23. In their responsive claim construction brief, Defendants offer the following alternative construction: "hardware, and/or software running on a processor, that identifies only ventricular beats." Defs.' Responsive Claim Construction Br. 19.

in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector." 207 Patent col.12 II.22-27. Defendants argue the fact the event generator must take into account variability caused by ventricular beats identified by the ventricular beat detector shows the system requires information regarding actual ventricular beats, as distinct from other regular or irregular beats.

Defendants also argue the specification confirms the ventricular beat detector must only provide information regarding ventricular beats for the claimed device to function properly. The significance of ventricular beats in identifying atrial fibrillation and atrial flutter events is that "[t]he occurrence of ventricular beats is generally unrelated to [such events]," *id.* col.9 II.15-16, and variability in beat-to-beat timing caused by ventricular beats is less likely to be indicative of atrial fibrillation and atrial flutter events, *see id.* col.10 II.12-16. To account for this decreased likelihood that variability in beat-to-beat timing associated with ventricular beats is indicative of atrial fibrillation and atrial flutter, interval comparisons associated with ventricular beats can be assigned a preset or "penalty" value for purposes of determining whether variability in the beat-to-beat timing is relevant to the onset or termination of atrial fibrillation or atrial flutter. Defendants argue in order for the system to function properly, the ventricular beat detector must identify only ventricular beats

The Court agrees that the claim language and specification contemplate that the ventricular beat detector must identify ventricular beats as distinct from other beats in the sense that it must identify which beats are ventricular beats. Otherwise, the system could not assign a penalty value to the interval comparisons associated with ventricular beats. Plaintiffs do not appear to dispute this point. *See* Pls.' Responsive Claim Construction Mem. 28 ("It is undisputed that the ventricular beat detector must identify ventricular beats."). The Court is not

persuaded, however, that this requirement means the ventricular beat detector must identify only ventricular beats. *See* '207 Patent col.10 II.1-3, 48-52 (noting the system can determine if the last three beats have been ventricular beats by determining if those beats "are marked with a ventricular beat occurrence indicator" received from a ventricular beat detector).

Because the Court is not persuaded the additional limitation proposed by Defendants is required by the specification or claims of the '207 patent, and because the parties otherwise agree on the meaning of the term "ventricular beat detector" (and this meaning is supported by the specification), the Court will construe the term "ventricular beat detector" to mean "hardware and/or software running on a processor that identifies ventricular beats."

2. "In Light of the Variability in the Beat-to-Beat Timing Caused by Ventricular Beats"

As described above, the device claimed in claim 1 includes "an event generator to generate an event when the variability in the beat-to-beat timing is identified as relevant to the at least one of atrial fibrillation and atrial flutter *in light of the variability in the beat-to-beat timing caused by ventricular beats* identified by the ventricular beat detector." '207 Patent col.12 II.22-27 (emphasis added). Plaintiffs argue a person of ordinary skill in the art would understand the term "in light of the variability in the beat-to-beat timing caused by ventricular beats," as used in the above claim limitation, to mean that the variability caused by ventricular beats must be taken into account in determining whether an atrial fibrillation or atrial flutter event has occurred. Plaintiffs therefore argue the term need not be construed.

Defendants contend the term "in light of the variability in the beat-to-beat timing caused by ventricular beats" is ambiguous in that it does not explain the relationship between the generation of an atrial fibrillation event and the variability caused by ventricular beats. Defendants agree the term requires that variability caused by ventricular beats be taken into

account in determining whether an atrial fibrillation event has occurred, but argue the specification reveals the event generator must make an adjustment for the variability caused by ventricular beats. Specifically, Defendants argue because the '207 patent teaches that ventricular beats are negatively indicative of atrial fibrillation, *id.* col.1 ll.61-65, col.10 ll.14-16, "an adjustment must be made to offset the distortion of the variability caused by ventricular beats when detecting atrial fibrillation based on heart rate variability." Defs.' Opening Claim Construction Br. 25. Defendants thus contend the disputed claim term should be construed to mean "adjusting for the effect of ventricular beats on the variability in beat-to-beat timing." *Id.* at 24.²²

Defendants rely primarily on figure 10, which shows a process for determining the variability in time intervals between successive heartbeats and "identifying if the variability is relevant to the onset of [atrial fibrillation or atrial flutter] while accommodating the variability caused by ventricular beats." '207 Patent col.9 ll.54-57. As part of this process, comparisons of intervals between successive heartbeats can be weighted according to the likelihood the comparisons are indicative of atrial fibrillation or atrial flutter. *See id.* col.9 l.64-col.10 l.11. Intervals associated with ventricular beats can be assigned a preset or "penalty" value reflecting the "decreased likelihood that the variability is indicative of an [atrial fibrillation or atrial flutter] event." *Id.* col.10 ll.14-16. The system can then calculate the average value of an entry in an array of the most recent beats using both the weighted and preset timing comparisons, and, if the

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²² In their responsive claim construction brief, Defendants propose the following alternative construction: "adjusting for the beat-to-beat timing caused by the ventricular beats." Defs.' Responsive Claim Construction Br. 23.

resulting average for the last five beats is greater than a predetermined value, the system triggers the start of an atrial fibrillation or atrial flutter event. *Id.* col.10 ll.26-31.²³

The process depicted in figure 10 involves adjusting for the effect of variability caused by ventricular beats on variability in beat-to-beat timing by assigning a penalty value to intervals associated with ventricular beats and using this penalty value in the calculation by which atrial fibrillation and atrial flutter events are identified. However, this particular adjustment is specifically addressed in dependent claim 2, which claims "[t]he device of claim 1, wherein the relevance determination logic is to accommodate variability in the beat-to-beat timing caused by ventricular beats by weighting ventricular beats as being negatively indicative of the one of atrial fibrillation and atrial flutter." Id. col.12 ll.28-32. The fact that claim 2 adds this limitation suggests it is not already required by claim 1. See Phillips, 415 F.3d at 1315. Defendants argue their proposed construction does not violate claim differentiation principles because the construction requires an "adjust[ment] for the effect of ventricular beats on the variability in beat-to-beat timing," and the weighting required in claim 2 is simply an example of a specific type of adjustment. But Defendants' proposed construction, although more broadly worded, is based on the weighting example in the specification. Moreover, claim 2 adds the weighting requirement as something done not by the device's "event generator" (the limitation in which the disputed claim term appears) but by its "relevance determination logic," which "identif[ies] a relevance of the variability in the beat-to-beat timing to at least one of atrial fibrillation and atrial flutter." '207 Patent col.12 ll.19-21. Because claim 2 already requires weighting ventricular

²³ Figure 11 shows a similar process for identifying if variability in time intervals between successive heartbeats is relevant to the termination of atrial fibrillation or atrial flutter. The process depicted in figure 11 includes the same assignment of a penalty value to intervals associated with ventricular beats, which is then used to calculate the average value of an entry in an array of the most recent beats and, if the average has dropped below a predetermined number, to trigger the end of an atrial fibrillation or atrial flutter event. *Id.* col.10 l.60–col.11 l.4.

beats as negatively indicative of atrial fibrillation by the relevance determination logic, the

further requirement of an adjustment by the event generator would be redundant.

For these reasons, the Court declines to adopt Defendants' proposed construction.

Because the Court agrees with Plaintiffs that the term "in light of the variability in the beat-to-

beat timing caused by ventricular beats" would be readily understood by a person of ordinary

skill in the art, the Court finds this term need not be construed.

An appropriate order follows.

BY THE COURT:

/s/ Juan R. Sánchez

Juan R. Sánchez, J.

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